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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,310	02/20/2004	Yegor Sinelnikov	TRANS 3.0-055	7812

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	**PAPER NUMBER**
3739	

MAIL DATE	DELIVERY MODE
07/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,310	SINELNIKOV ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,10 and 83-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9,10 and 83-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 3, 2008 has been entered.

It is noted that a Petition to revive the application as being unintentionally abandoned (petition filed with the RCE) has been granted (petition decision mailed March 24, 2008).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 9, 10, 83-87 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al (5,575,766) in view of the teaching of Tu et al (5,971,968).

Swartz et al disclose a catheter device having a tip electrode for creating lesions in atrial tissue to correct atrial arrhythmia. Swartz et al disclose the steps of providing the ablation device into the atria (see Figures) and advancing the device along specific tracks to create lesions. The operation of the device does not require location of the

device within the pulmonary vein or the ostium, though certain tracks may be made in the general vicinity of these sites. The catheter in no way forcibly engages the wall of a pulmonary vein as the lesion tracks are created solely on the atrial wall surface. Swartz et al fail to disclose the injection of a contrast medium during the procedure to facilitate x-ray viewing of the location of the catheter.

Tu et al disclose a device that is structurally very similar and is used for the ablation of cardiac tissue. Specifically, Tu et al disclose that the device may be used to ablate tissue within the pulmonary veins. Tu et al specifically teach that it is advantageous to provide a lumen for providing a contrast medium through the device and distal to the tip electrode to facilitate x-ray visualization during the ablation procedure and to accurately locate the catheter tip at a desired location.

The examiner maintains that the various steps of injecting the contrast medium in a pulmonary vein would obviously be performed for those track ablations that occur in the vicinity of the pulmonary veins and that one of ordinary skill in the art would be fully capable of ascertaining the location of the catheter at such treatment sites. Moreover, the specific times for acquiring images (e.g. while the catheter is against the wall or after it has been removed from the wall) would be well within the purview of the skilled artisan as imaging would obviously be performed at any time during the procedure deemed necessary by the user to ascertain the location of the catheter device.

To have provided the Swartz et al catheter device with a means to inject a contrast medium so as to ascertain the specific location of the catheter device within the atrium would have been an obvious consideration for one of ordinary skill in the art,

particularly since Tu et al teach that it is known to use such a location means in a similar catheter device.

Claims 7, 9, 10 and 83-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al (6,146,379) in view of the teaching of Tu et al ('968).

Fleischman et al disclose another catheter device for treating atrial arrhythmias. Fleischman et al disclose numerous embodiments for catheters to be inserted into the atria for creating lesions, and also specifically disclose the use of imaging to accurately locate the device (col. 9, lines 40-41), but fail to specifically disclose the use of a contrast medium and x-ray visualization. Among the embodiments are linear catheters, expandable spline catheters and a balloon catheter. It is noted that Fleischman et al disclose the creation of lesions on the atrial surface, as well as around the pulmonary veins, but does not disclose creating lesions within the pulmonary veins or otherwise securing the device within the pulmonary veins.

As addressed above, Tu et al disclose a device that is structurally very similar and is used for the ablation of cardiac tissue. Specifically, Tu et al disclose that the device may be used to ablate tissue within the pulmonary veins. Tu et al specifically teach that it is advantageous to provide a lumen for providing a contrast medium through the device and distal to the tip electrode to facilitate x-ray visualization during the ablation procedure and to accurately locate the catheter tip at a desired location.

The examiner maintains that the various steps of injecting the contrast medium in a pulmonary vein would obviously be performed for those track ablations that occur in

the vicinity of the pulmonary veins and that one of ordinary skill in the art would be fully capable of ascertaining the location of the catheter at such treatment sites. Moreover, the specific times for acquiring images (e.g. while the catheter is against the wall or after it has been removed from the wall) would be well within the purview of the skilled artisan as imaging would obviously be performed at any time during the procedure deemed necessary by the user to ascertain the location of the catheter device.

To have provided the Fleischman et al catheter device with a means to inject a contrast medium so as to ascertain the specific location of the catheter device within the atrium would have been an obvious consideration for one of ordinary skill in the art, particularly since Tu et al teach that it is known to use such a location means in a similar catheter device.

Claims 89-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al ('766) and Tu et al ('968) as applied to claim 10 above, and further in view of the teaching of Lennox et al (5,571,088).

The combination of the Tu et al teaching with the Swartz et al system has been previously addressed. Swartz et al also fail to specifically disclose a balloon device for securing the ablation tip within the atrium.

Lennox et al disclose another ablation device for creating lesions on the atrial surface, and specifically teach that it is known to provide a balloon on an ablation catheter device for securing the device into engagement with the atrial wall during ablation procedures (see Abstract).

To have provided the Swartz et al device, as modified by the teaching of Tu et al, with a balloon member for securing the device during atrial ablation would have been an obvious design consideration for the skilled artisan since Lennox et al fairly teach that it is known to use a balloon for such a purpose on an atrial ablation catheter.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tu et al (6,217,576) discloses another ablation catheter having a means to inject a contrast medium to facilitate x-ray viewing, and Swanson et al (6,514,246) disclose another atrial ablation device having various embodiments for catheters used to create lesions on the atrial surface.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
July 25, 2008